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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,903	10/27/2000	Brigitte Weston	514412-2020.1	8217

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

19

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/698,903

Applicant(s)

WESTON ET AL.

Examiner

Anne Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-36 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with the application is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 23-24 and 33-34 have been amended and claims 35-36 have been added, as requested in Paper No. 18, filed 25 November 2002. Claims 23-36 are pending. Claims 23-28, previously withdrawn from consideration as being drawn to non-elected inventions, are now examined, because amendment has made them part of the elected Group. Claims 29-32 remain withdrawn from consideration as being drawn to a nonelected invention. Claims 23-28 and 33-36 are examined.
2. The rejection of claims 33-34 under 35 U.S.C. 112, first paragraph, for lack of enablement with respect to a deposit requirement is WITHDRAWN.

Claim Objections

3. Claims 23-27 and 31-36 are objected to because of the following informalities:

All instances of "No." in claims 23-27 and 31-36 should be replaced with --NO:--.

The comma after "SEQ ID No. 8" in claims 25-26 should be deleted.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claim 23-28 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying elite event MS-B2 in transgenic Brassica or confirming seed purity using TAIL-PCR and primers SEQ ID NOs:4-7 and 9 or PCR

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using SEQ ID NOs:11-14, does not reasonably provide enablement for a method of identifying elite event MS-B2 in transgenic Brassica or confirming seed purity using PCR with any primer or using any other hybridization method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 22 August 2002, as applied to claims 33-34. Applicant's arguments filed 25 November 2002 have been fully considered but they are not persuasive.

The claims are broadly drawn to a method of identifying elite event MS-B2 in transgenic Brassica or confirming seed purity using any probe or primer that hybridizes with the 5' flanking region or SEQ ID NO:8 or 3' flanking region of SEQ ID NO:10 or a primer that "recognizes" any sequence within any "foreign DNA".

The instant specification, however, only provides guidance for transformation of *Brassica napus* with a plasmid, pTCO113, comprising a nucleic acid encoding barnase under control of a tapetum specific promoter (example 1); characterization of transgenic events by Southern analysis and analysis of plant phenotype with respect to agronomic characteristics compared to non-transformed plants and with respect to restoration of male fertility when crossed to a fertility restorer line, which found one plant, MS-B2, which had optimal expression of genes comprising on the transforming plasmid (example 2); characterization of the elite MS-B2 event by Southern hybridization with a barnase-promoter probe amplified from pTCO113 with SEQ ID NOs:2 and 3, identification of the flanking regions, SEQ ID NOs:8 and 10, using TAIL-PCR and primers SEQ ID NOs:4-7 and 9, and Southern blot analysis of several generations of MS-B2 progeny to test for stability of the event (example 3); backcrossing the event into *B. juncea*, *B. napus*, and *B.*

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rapa, where it continued to behave as an elite event (example 4), and development of diagnostic tools for the MS-B2 elite event by Southern blotting with the probe amplified from pTCO113 or by PCR with SEQ ID NOs:11-14.

The instant specification fails to provide guidance for any probe or primer that hybridizes with the 5' flanking region or SEQ ID NO:8 or 3' flanking region of SEQ ID NO:10 or a primer that "recognizes" any sequence within any "foreign DNA" other than SEQ ID NOs:4-7, 9 and 11-14. The specification fails to provide guidance for producing a DNA fragment of between 160-200 base pairs using any primer that "recognizes" the 5' flanking region or SEQ ID NO:8 or 3' flanking region of SEQ ID NO:10 and using any primer that "recognizes" any sequence within any "foreign DNA".

The instant specification also fails to teach the "MS-B2 PCR Identification Protocol" (claims 27-28).

Furthermore, the specification fails to teach how detection of the presence of an MS-B2 specific region or how the failure to detect the presence of an MS-B2 specific region in a batch of seeds will confirm that the entire batch is pure (claims 33 and 35). Detection of the presence of an MS-B2 specific region could mean that some seeds have the region, while others do not. Failure to detect the presence of an MS-B2 specific region would only mean that no seeds have that region, but does not mean that all the seeds are genetically identical or that the seeds are free of non-seed impurities.

Given the claim breadth and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

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Applicant urges that the examples are replete with procedures for using the specific primers and probes (response pg 4-7).

This is not found persuasive because the specification fails to teach the methods within the full scope of the claims.

6. Claims 23-28 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 22 August 2002, as applied to claims 33-34. Applicant's arguments filed 25 November 2002 have been fully considered but they are not persuasive.

The claims are broadly drawn to a method of identifying elite event MS-B2 in transgenic Brassica or a method of confirming seed purity using any probe or primer that hybridizes with the 5' flanking region or SEQ ID NO:8 or 3' flanking region of SEQ ID NO:10 or a primer that "recognizes" any sequence within any "foreign DNA". In contrast the only primers described in the specification are SEQ ID NOs:4-7, 9 and 11-12. Applicant does not describe other primers encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the sequences are not described, the methods of using the sequences to identify elite event MS-B2 in transgenic Brassica or confirm seed purity are likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

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Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Applicant urges that specific primers are identified by SEQ ID NO: in the specification (response pg 4-7). This is not found persuasive because the primers are not described within the full scope of the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 23-28 and 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 22 August 2002, as applied to claims 33-34. Applicant's arguments filed 25 November 2002 have been fully considered but they are not persuasive.

Claims 23-26 and 33-36 are indefinite in their recitation of "flanking region". The flanking regions of SEQ ID NOs:8 and 10 are not defined. Applicant urges that "flanking region is defined on pg 12, lines 15-23, of the specification and on pg 32-33 the 5' flanking region of SEQ ID NO:8 and the 3' flanking region of SEQ ID NO:10 are identified as bases 1-234 and 194-416 respectively (response pg 4). This is not found persuasive because those regions are only identified as plant DNA, not as flanking regions. It is suggested that "5' flanking region of SEQ ID NO:8" be replaced with --bases 1-234 of SEQ ID NO:8-- and "3' flanking region of SEQ ID NO:10" be replaced with --bases 194-416 of SEQ ID NO:10--.

The following rejections are new:

In claim 23 "detection of" in line 3 should be expressed as the gerund form of a verb.

It is unclear in claims 23 and 33-36 in what the detection occurs. Seed? DNA? Whole plant tissue?

Claim 23 is indefinite in its recitation of "specifically recognizes" in line 4. What level of recognition is considered specific and what conditions/steps are required to achieve specific recognition are unclear. Similarly, claims 24-26 and 36 are indefinite in their recitation of "recognizes".

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In claim 25, one of the primers already recognizes a sequence within the foreign DNA (see claim 24). Is this an unnecessary repetition or is the primer used in some other step?

Claim 24 lacks antecedent basis for the limitation "the foreign DNA" in line 6.

In claim 24 it is unclear where the amplification step occurs relative to the detection step of claim 24.

Claim 27 lacks antecedent basis for the limitation "the MS-B2 PCR identification protocol" in line 2. Additionally, it is unclear what steps are involved in the protocol and where those steps occur in relation to the detection step of claim 23 and the amplification step of claim 24. Similarly, it is unclear in which step, the detection step, the amplification step or the 'protocol' step, the primers are used. Additionally, it is not clear to what SEQ ID NOs:11 and 12 correspond - the 5' flanking region, the 3' flanking region or the sequence within the foreign DNA. Clarity with respect to this is particularly required because of the recitation of "respectively".

In claim 28, it is unclear where the step of amplifying a fragment of 183 bp occurs in relationship to the detection, amplification and 'protocol' steps

Claims 33-34 and 35 are indefinite in their recitation of "specifically hybridizes" in lines 3, 3, and 2-3, respectively. What level of hybridization is considered specific and what conditions are required to achieve specific hybridization are unclear.

Claim 35 is indefinite for failing to recite active, positive method steps. Not detecting a sequence is not a positive method step. Additionally, it is unclear what the not-detecting step comprises - doing a Southern blot, growing a plant, closing one's eyes, all of which are steps that might not detect something.

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Claim 36 is indefinite in its recitation of "using a polymerase chain reaction". The PCR steps should be recited as active, positive steps delimiting how this use is actually practiced.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 23-26 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,509,516. The rejection is repeated for the reasons of record set forth in a provisional rejection in the Office action mailed 22 August 2002, as applied to claims 33-34. Applicant's arguments filed 25 November 2002 have been fully considered.

Applicant urges that a terminal disclaimer will be filed if examiner believes that allowable claims in the instant application overlap with the cited application (now an issued patent), and requests abeyance until that time (response pg 3). This rejection will be held in abeyance until such a time.

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same

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invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 27-28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9-10 of prior U.S. Patent No. 6,509,516. This is a double patenting rejection.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
February 21, 2003



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